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(54) **EMBOLIC PROTECTION DEVICE WITH AN INTEGRAL BASKET AND BAG**

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(57) **ABSTRACT**

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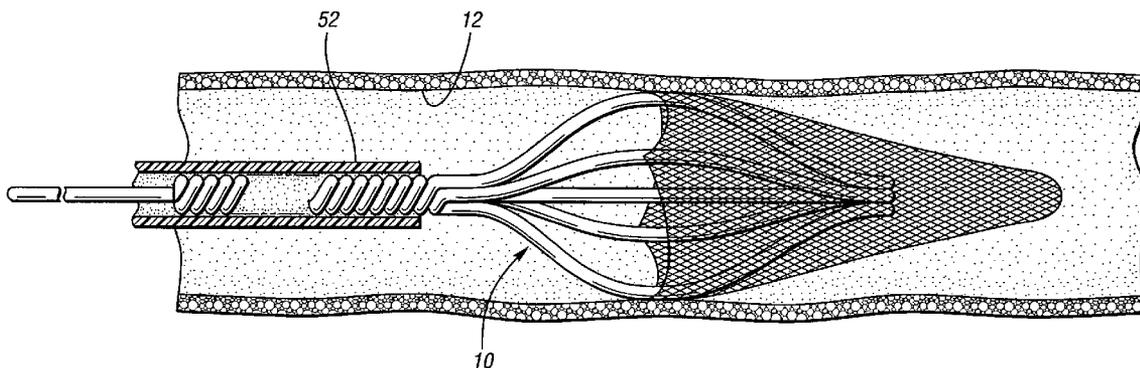
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Related U.S. Application Data

(60) Provisional application No. 60/698,350, filed on Jul. 12, 2005.

An embolic protection device includes a basket defined by a section of a set of wires arranged as a plurality of struts. These struts are coupled together at their distal ends as well as to the distal end of a core wire or mandrel. Another section of the wires spirals around the core wire to define a hollow channel in which the core wire can reciprocate. Thus, pulling or pushing a proximal end of the core wire relative to the struts expands or contracts the basket. A filter bag is attached to the basket for capturing clots when the basket is in an expanded configuration.



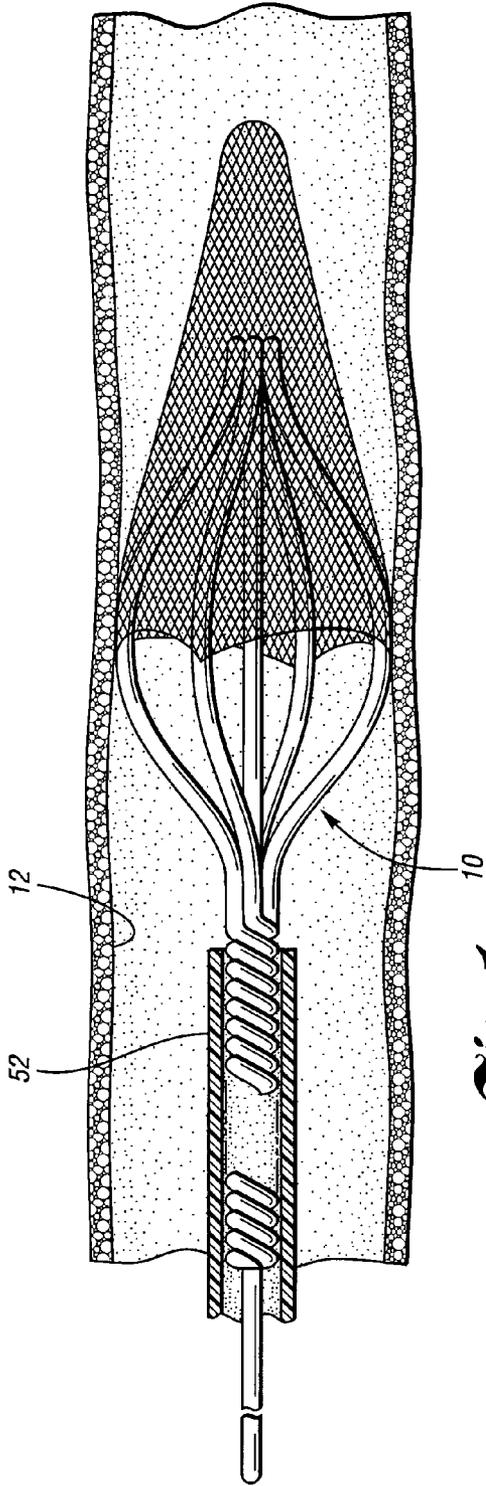


Fig. 1

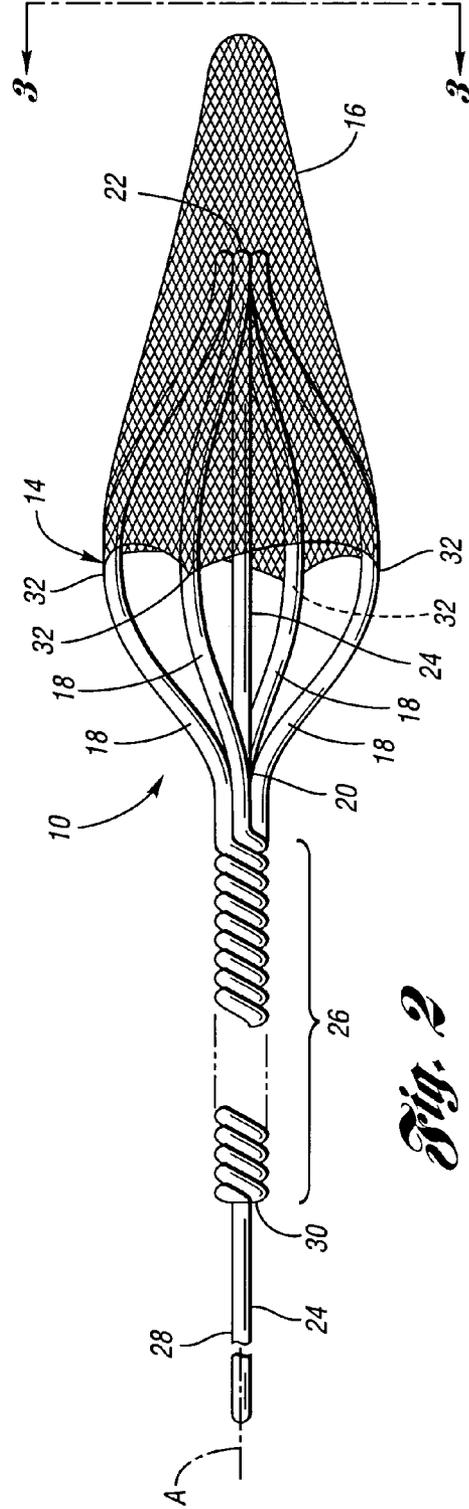


Fig. 2

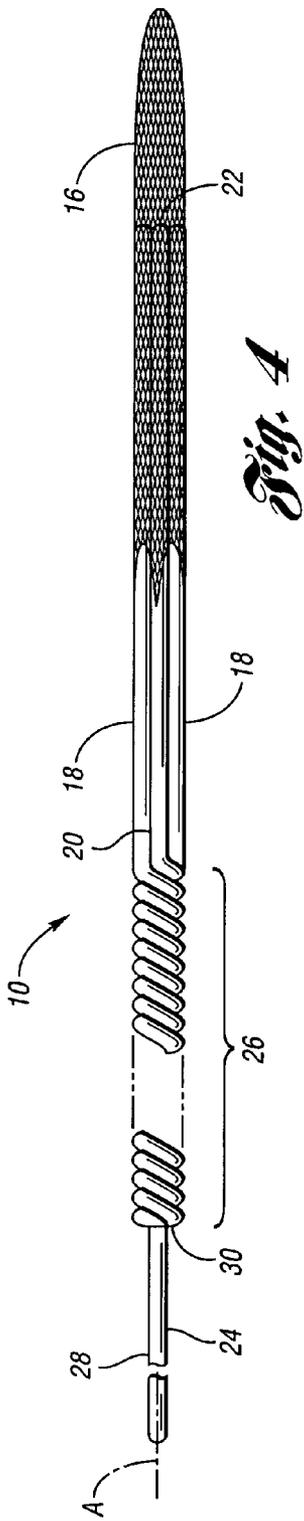


Fig. 4

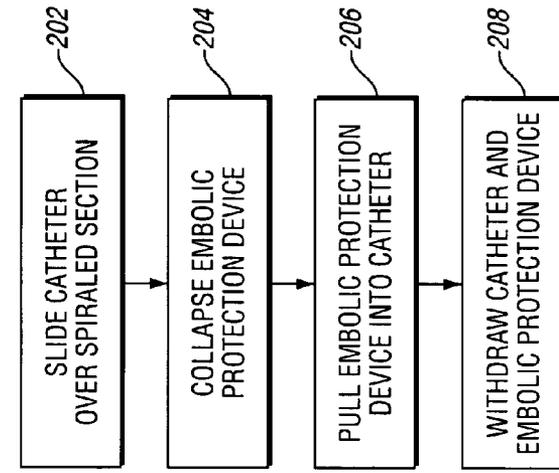


Fig. 7

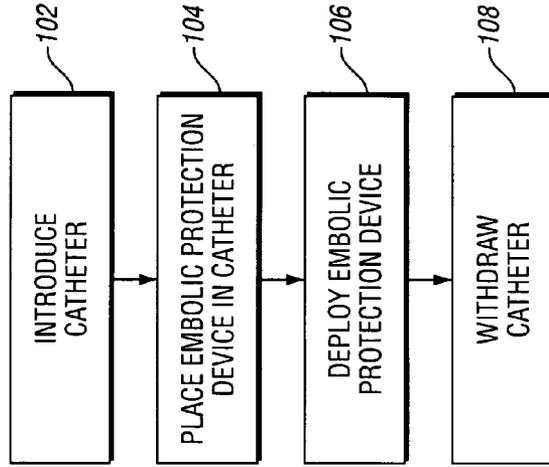


Fig. 6

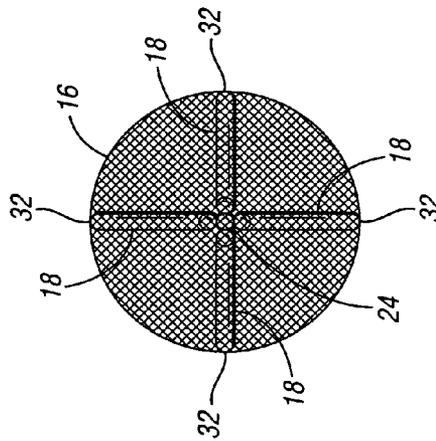


Fig. 3

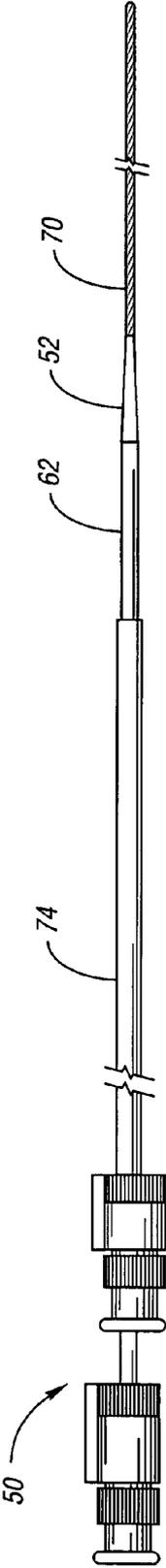


Fig. 5a

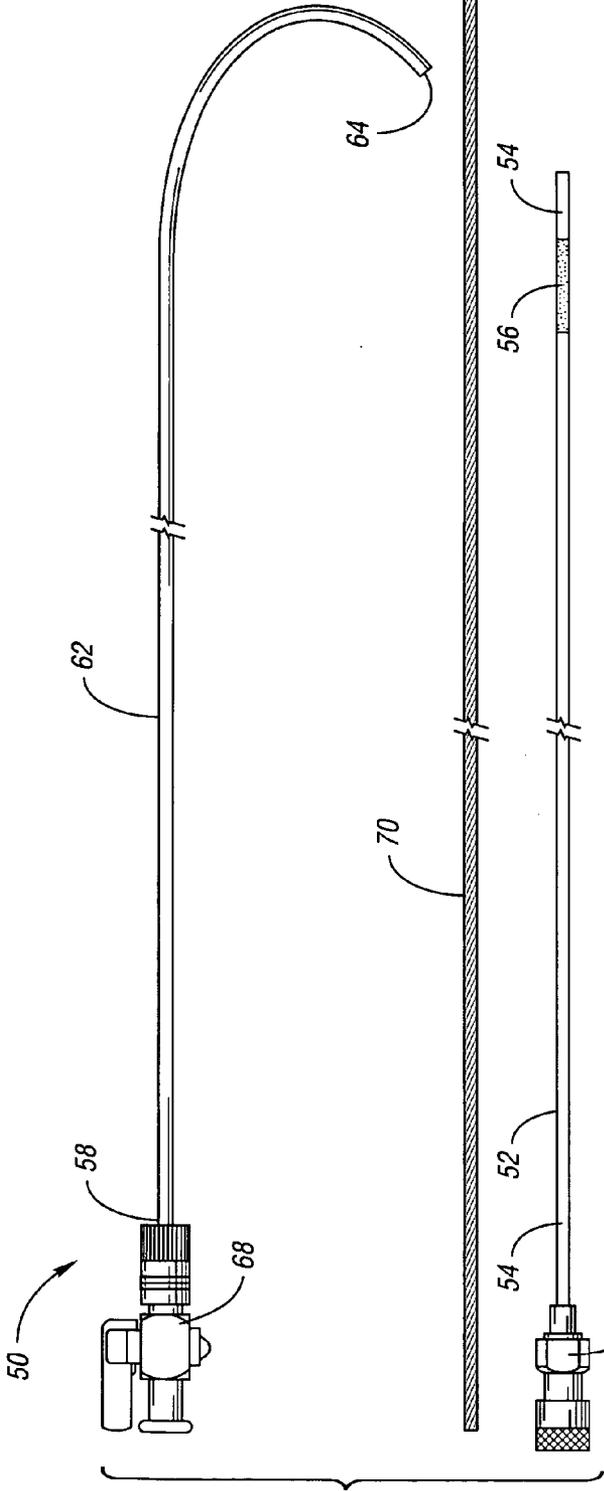


Fig. 5b

EMBOLIC PROTECTION DEVICE WITH AN INTEGRAL BASKET AND BAG

RELATED APPLICATION

[0001] This application claims the benefit of U.S. Provisional Application No. 60/698,350, filed Jul. 12, 2005, the entire contents of which are incorporated herein by reference.

BACKGROUND

[0002] The present invention relates to medical devices. More particularly, the present invention relates to embolic protection devices and methods for capturing emboli within a body vessel.

[0003] The present invention relates to medical devices. More particularly, the present invention relates to embolic protection devices and methods for capturing emboli within a body vessel.

[0004] Presently, there are a number of treatments for embolic protection to prevent emboli and blood clots from traveling within the vasculature that create undesirable medical conditions, such as ischemic stroke, brain aneurysm, and pulmonary embolism. For example, vena cava filters are commonly employed to trap blood clots and emboli in the vena cava filter to prevent pulmonary embolism; snares and baskets (for example, stone retrieval baskets) are generally employed to retrieve urinary calculi; and occlusion coils are typically employed to occlude aneurysms and accumulate thrombi in a body vessel.

[0005] Treatments for stenotic lesions create a potential in releasing blood clots and other thrombi plaque in the vasculature of the patient, for example, in the treatment for carotid artery stenosis. Generally, carotid artery stenosis (also called carotid artery disease) is the narrowing of the carotid arteries, which are the main arteries in the neck that supply blood to the brain, usually caused by plaque build-up in the carotid artery, creating a relatively high risk factor for ischemic stroke. Plaque forms when cholesterol, fat and other substances form in the inner lining of an artery. This formation process is known as atherosclerosis.

[0006] Depending on the degree of stenosis and the patient's overall condition, carotid artery stenosis has been treated with surgery. This procedure, known as carotid endarterectomy, removes the plaque from the arterial walls. Carotid endarterectomy has been shown to benefit patients with arteries that are substantially narrowed, for example, by about 70% or more. For people with arteries that are not as narrowed, for example, less than about 50%, an anti-clotting drug, such as anti-platelet agents and anticoagulants, may be prescribed to reduce the risk of ischemic stroke.

[0007] Carotid angioplasty is a more recently developed treatment for carotid artery stenosis. This treatment uses balloons with or without stents to open a narrowed artery. This procedure can be performed through a standard percutaneous transfemoral approach with the patient anesthetized using light intravenous sedation. At the stenosis area, an angioplasty balloon is delivered to predilate the stenosis in preparation for placement of a stent. The balloon is then removed and exchanged through a catheter for a stent delivery device. Once in position, a stent is deployed across the stenotic area. If needed, another balloon can be placed

inside the deployed stent for post-dilation to ensure that the struts of the stent are pressed firmly against the inner surface of the vessel wall.

[0008] During the stenosis procedure, there is a risk of blood clots and thrombi being undesirably released into the blood flow within the vasculature. Embolic or distal protection devices have been implemented to capture emboli. However, many current embolic protection devices restrict flow when deployed within the vasculature of the patient. Moreover, many embolic protection devices are relatively difficult to collapse and retrieve after the need for such a device in the vasculature passes.

[0009] In view of the above, it is apparent that there exists a need for an improved device and method for distally protecting and capturing emboli within a body lumen during a stenosis procedure.

SUMMARY

[0010] The present invention generally provides an embolic protection device that minimizes restricted flow when deployed within the vasculature of a patient and that is relatively easy to retrieve after the risk of releasing blood clots and thrombi within the vasculature has passed. The embolic protection device includes a basket defined by a section of a set of wires arranged as a plurality of struts. These struts are coupled together at their distal ends as well as to the distal end of a core wire or mandrel. Another section of the wires spirals around the core wire to define a hollow channel in which the core wire can reciprocate. Thus, pulling or pushing a proximal end of the core wire relative to the spiraled section expands or contracts the basket. A filter bag is attached to the basket for capturing emboli when the basket is in an expanded configuration.

[0011] Hence, the filter bag, basket, and deployment mechanism are all one integral unit with a small cross sectional profile when the device is in a collapsed configuration. Thus, during delivery of the device, the small profile enables crossing a lesion without inadvertently dislodging material from the lesion site.

[0012] Further features and advantages will be apparent from the following description, and from the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] FIG. 1 is an environmental view of an embolic protection device in accordance with one embodiment of the present invention;

[0014] FIG. 2 is a perspective view of the embolic protection device of FIG. 1;

[0015] FIG. 3 is a end view of the embolic protection device of FIG. 1;

[0016] FIG. 4 is a side view of the embolic protection device in a collapsed configuration in accordance with one embodiment of the present invention;

[0017] FIG. 5a is a side view of an embolic protection assembly for capturing emboli during treatment of a stenotic lesion in accordance with one embodiment of the present invention;

[0018] FIG. 5b is an exploded side view of the assembly in FIG. 5a;

[0019] FIG. 6 is a flow chart of one method for embolic protection during treatment of a stenotic lesion in a body vessel; and

[0020] FIG. 7 is a flow chart of one method for retrieving an embolic protection device for post-treatment of a stenotic lesion in a body vessel.

DETAILED DESCRIPTION

[0021] Referring now to FIG. 1, an embolic protection device embodying the principles of the present invention is illustrated therein and designated at 10. The device 10 captures emboli during treatment of a stenotic lesion in a body vessel 12 in accordance with an embodiment of the present invention. As shown in FIGS. 1 and 2, the device 10 includes a basket 14 and a filter portion or bag 16 attached to the basket 14 for capturing emboli in the body vessel 12. The basket 14 is defined by a section of a set of wires arranged as struts 18 that extend longitudinally from a proximal end 20 of the basket 12 to a distal end 22. A distal end of a core wire 24 is attached to the distal end 22 of the struts 18. Another section of the set of wires is twisted or spiraled to define a spiraled section 26 with a hollow channel through which the core wire 24 extends along a longitudinal axis A. A proximal end 28 of the core wire 24 extends beyond a proximal end 30 of the spiraled portion 26. The distal end of the core wire 24 is attached or coupled to the distal end 22 of the struts 18 by solder, or the distal ends may be embedded in a plastic material. The lip of the filter bag 16 is attached to the basket 14 only at attachments 32 of the struts 18 to define an opening into which clots or emboli flow when the filter is deployed in the vasculature. The attachments 32 may be glue or solder or any other biocompatible attachment mechanism. When in the expanded configuration, the struts 18 extend longitudinally and curve outwardly between the proximal end 20 of the basket 14 and the distal end 22. The attachments 32 are typically located on the struts 18 approximately where the basket achieves its maximum diameter when expanded so that blood flows through the filter bag 16 and not around it.

[0022] Since the core wire 24 is attached only at the distal end 22 of the basket 14 and is able to reciprocate within the hollow channel of the spiraled section 26, grasping the proximal end 28 of the core wire 24 and pulling it relative to the proximal end 30 of the spiraled section 26, buckles the section of the struts 18 to expand the basket 14, and hence the filter bag 16. Conversely, pushing the core wire 24 relative to the spiraled section 26 collapses the basket 14 and bag 16 for delivery or retrieval of the device 10. This feature allows a catheter to ride over the spiraled section 26 and the struts 18 for relatively easy collapse and retrieval of the device 10. As shown in FIGS. 2 and 3, four wires define the basket 14 and the spiraled section 26. However, depending on the application, as few as three or more than four struts may be employed.

[0023] FIG. 4 illustrates the device 10 in its collapsed or closed state in accordance with one embodiment of the present invention. As shown, the device 10 has a reduced diameter, occupying a cross-sectional profile less than the outer diameter of the device 10 in the expanded state. The struts 18 are generally straight and the bag 16 is collapsed about a portion of the struts 18. The portion of the bag 16 extending beyond the distal end 22 of the struts 18 may be folded back over the struts 18 for delivery of the device 10.

[0024] The struts 18 may be formed from any suitable material such as a superelastic material, stainless steel wire, cobalt-chromium-nickel-molybdenum-iron alloy, or cobalt-chrome alloy. It is understood that in some implementations the struts 18 may be formed of any other suitable material that will result in a self-opening or self-expanding basket 14, such as shape memory alloys. Shape memory alloys have the desirable property of becoming rigid, that is, returning to a remembered state, when heated above a transition temperature. A shape memory alloy suitable for the present invention is Ni—Ti available under the more commonly known name Nitinol. When this material is heated above the transition temperature, the material undergoes a phase transformation from martensite to austenite, such that material returns to its remembered state. The transition temperature is dependent on the relative proportions of the alloying elements Ni and Ti and the optional inclusion of alloying additives.

[0025] In one embodiment, the struts 18 are made from Nitinol with a transition temperature that is slightly below normal body temperature of humans (that is, about 98.6° F.). Thus, when the basket 14 is deployed in a body vessel and exposed to normal body temperature, the alloy of the basket 14 will transform to austenite, that is, the remembered state, which for certain implementations is the expanded configuration when the basket 14 is deployed in the body vessel. To remove the basket 14, the basket 14 is cooled to transform the material to martensite, which is more ductile than austenite, making the basket 14 more malleable, and hence more easily collapsible by pushing the core wire 24 relative to the spiraled section 26 and then pulling the device 10 into a lumen of a catheter for removal.

[0026] In other embodiments, the basket 14 may be self-closing or self-collapsing. In such embodiments, the struts 18 may be made from Nitinol with a transition temperature that is above normal body temperature of humans. Thus, when the basket 14 is deployed in a body vessel and exposed to normal body temperature, the basket 14 is in the martensitic state so that the basket 14 is sufficiently ductile to bend or form the basket 14 into an expanded configuration. To remove the basket 14, it is heated, for example, with a saline solution, to transform the alloy to austenite so that the basket 14 becomes rigid and returns to a remembered state, that is, a collapsed configuration.

[0027] The filter bag 16 may be formed from any suitable material to be used for capturing emboli from the stenotic lesion during treatment thereof while allowing blood to flow through it. In one embodiment, the filter bag 16 is made of connective tissue material for capturing emboli. The connective tissue may include extracellular matrix (ECM), which is a complex structural entity surrounding and supporting cells that are found within mammalian tissues. More specifically, ECM includes structural proteins (for example, collagen and elastin), specialized protein (for example, fibrillin, fibronectin, and laminin), and proteoglycans, a protein core to which are attached long chains of repeating disaccharide units termed glycosaminoglycans.

[0028] The extracellular matrix can be made of small intestinal submucosa (SIS). As known, SIS is a resorbable, acellular, naturally occurring tissue matrix composed of ECM proteins and various growth factors. SIS is derived from the porcine jejunum and functions as a remodeling bioscaffold for tissue repair. SIS has characteristics of an

ideal tissue engineered biomaterial and can act as a bioscaffold for remodeling of many body tissues including skin, body wall, musculoskeletal structure, urinary bladder, and also supports new blood vessel growth. In many aspects, SIS is used to induce site-specific remodeling of both organs and tissues depending on the site of implantation. In theory, host cells are stimulated to proliferate and differentiate into site-specific connective tissue structures, which have been shown to completely replace the SIS material in time.

[0029] In some implementations, SIS is used to temporarily adhere the filter bag 16 to the walls of a body vessel in which the device 10 is deployed. SIS has a natural adherence or wettability to body fluids and connective cells that form the connective tissue of a body vessel wall. Because of the temporary nature of the duration in which the device 10 is deployed in the body vessel, host cells of the wall will adhere to the filter bag 16 but will not differentiate, allowing for retrieval of the device 10 from the body vessel.

[0030] In other embodiments, the filter bag 16 may be made of a mesh/net cloth, nylon, polymeric material, Teflon, or woven mixtures thereof.

[0031] In use, the device 10 expands from the collapsed state to the expanded state, engaging the basket 14 with the body vessel. In turn, the filter portion 16 expands to capture emboli during treatment of the stenotic lesion. After the device 10 is no longer needed, it may be retrieved. In some embodiments, a catheter is deployed longitudinally about the basket 14 after it has been collapsed by pulling on the core wire 24 relative to the spiraled section 26.

[0032] The embolic protection device 10 may be used independently without any other delivery system or mechanism. Alternatively, the device 10 may be used, for example, with an embolic protection assembly 50 as depicted in FIGS. 5a and 5b.

[0033] As shown, the assembly 50 includes a balloon catheter 52 having a tubular body 54 and an expandable balloon 56 attached to and in fluid communication with the tubular body 54 for angioplasty at a stenotic lesion. The assembly 50 also includes the embolic protection device mentioned above. The tubular body 54 is preferably made of soft flexible material such as silicon or any other suitable material. The balloon catheter 52 may include an outer lumen that is in fluid communication with the balloon 56 for inflating and deflating the balloon 56 and an inner lumen formed within the outer lumen for percutaneous guidance through the body vessel with a wire a guide and for deploying the embolic protection device 10. In certain implementations, the balloon catheter 52 has a proximal fluid hub 72 in fluid communication with the balloon 56 by way of the outer lumen for fluid to be passed through the outer lumen for inflation and deflation of the balloon 56 during treatment of the stenotic lesion.

[0034] The assembly 50 further includes an inner catheter 62 with a distal end 64 through which the balloon catheter 52 is disposed for deployment in the body vessel. The inner catheter 62 is preferably made of a soft, flexible material such as silicon or any other suitable material. Generally, the inner catheter 62 also has a proximal end 58 and a plastic adaptor or hub 68 to receive the embolic protection device 10 and balloon catheter 52. The size of the inner catheter 62 is based on the size of the body vessel into which the catheter 62 is inserted, and the size of the balloon catheter 52.

[0035] The assembly 50 may also include a wire guide 70 configured to be percutaneously inserted within the vascu-

lature to guide the inner catheter 62 to a location adjacent a stenotic lesion. Alternatively, the embolic protection device 10 may be employed as a wire guide.

[0036] To deploy the embolic protection device 10, the device 10 is placed in the inner lumen of the balloon catheter 52 prior to treatment of the stenotic lesion. The distal protection device is then guided through the inner lumen preferably from the hub 72 and distally beyond the balloon 56 of the balloon catheter 52, exiting from the distal end of the balloon catheter 52 to a location within the vasculature downstream of the stenotic lesion.

[0037] The assembly 50 may include a polytetrafluoroethylene (PTFE) introducer sheath 74 for percutaneously introducing the wire guide 70 and the inner catheter 62 in a body vessel. Of course, any other suitable material may be used. The introducer sheath 74 may have any suitable size, e.g., between about three-french to eight-french. The introducer serves to allow the inner and balloon catheters 62, 52 to be inserted percutaneously to a desired location in the body vessel. The introducer sheath 74 receives the inner catheter 62 and provides stability to the inner catheter at a desired location of the body vessel. For example, as the introducer sheath 74 is held stationary within a common visceral artery, it adds stability to the inner catheter 62, as the inner catheter 62 is advanced through the introducer sheath 74 to a dilatation area in the vasculature.

[0038] When the distal end 64 of the inner catheter 62 is at a location downstream of the dilatation area in the body vessel, the balloon catheter 52 is inserted through the inner catheter 62 to the dilatation area. The embolic protection device 10 is then loaded at the proximal end of the balloon catheter 52 and is advanced coaxially through the inner lumen of the balloon catheter 52 for deployment through the distal end of the balloon catheter. In this embodiment, the proximal end 28 of the core wire 24 can be used to mechanically advance or push the embolic protection device 10 through the catheter.

[0039] FIG. 6 depicts a sequence of steps of a process 100 for embolic protection during treatment of stenotic lesion in a body vessel. The process 100 includes percutaneously introducing the balloon catheter 52 in a body vessel in a step 102, after the inner catheter 62 is disposed to a dilatation area within the body vessel. The physician may use any suitable means, for example, fluoroscopy, of verifying the placement of the balloon catheter at a dilatation area.

[0040] Next, in step 104, the embolic protection device 10 is placed in the collapsed state in the inner lumen of the balloon catheter 52 and advanced beyond the distal end of the balloon catheter, and, hence, beyond the dilatation area. The process 100 further includes deploying the device in an expanded state downstream from the stenotic lesion to capture emboli during treatment of the stenotic lesion in step 106. Optionally, the catheter may be withdrawn in step 108, and an alternative treatment device may be placed over the spiraled section 26 of the embolic protection device 10, that is, the device 10 may serve as a wire guide for the alternative treatment device.

[0041] In yet another example of the present invention, FIG. 7 depicts a process 200 for retrieving an embolic protection device for post-treatment of a stenotic lesion in a body vessel. In step 202, the process 200 includes sliding a catheter, such as the balloon catheter 52, over the spiraled section 26 of the embolic protection device 10 when the device is in a deployed state within the body vessel in step

202. Next, in step 204, the core wire 24 is pushed relative to the spiraled section 26 to collapse the basket 14, as well as the bag 16. The process 200 further includes, in step 206, retracting the embolic protection device 10 into the balloon catheter, and, in step 208, retrieving the catheter and the embolic protection device from the body vessel.

[0042] The above and other embodiments are within the scope of the following claims.

What is claimed is:

1. An embolic protection device for capturing emboli during treatment of a stenotic lesion in a body vessel, the device comprising:

a set of wires, a section of which is arranged as struts defining a basket with a distal end and a proximal end, the basket having an expanded state and a collapsed state, the set of wires including a spiraled section that defines a hollow channel extending from the proximal end of the basket to a proximal end of the spiraled section;

a core wire with a distal end coupled to the distal end of the basket, the core wire extending from the distal end of the basket through the hollow channel to a proximal end of the core wire that extends beyond the proximal end of the spiraled section; and

a filter bag with a lip attached to the struts only at attachments located on the struts generally where the basket achieves its maximum diameter when the basket is in the expanded state for capturing emboli,

movement of the core wire in the proximal direction relative to the spiraled section causing the basket, and hence the filter bag, to open to the expanded state, and movement of the core wire in the distal direction relative to the spiraled section causing the basket, and hence to the filter bag, to close to the collapsed state.

2. The device of claim 1 wherein the number of struts is four.

3. The device of claim 1 wherein the opening of the filter bag faces toward the stenotic lesion.

4. The device of claim 1 wherein the filter bag is made of a mesh material.

5. The device of claim 1 wherein the filter bag is made of connective tissue including extracellular matrix.

6. The device of claim 5 wherein the extracellular matrix is made of small intestinal submucosa.

7. The device of claim 1 wherein the set of wires is made of shape memory material with a transition temperature.

8. The device of claim 1 wherein the set of wires is made of superelastic material.

9. The device of claim 8 wherein the superelastic material is Nitinol.

10. An embolic protection device for capturing emboli during treatment of a stenotic lesion in a body vessel, the device comprising:

a basket with a set of struts extending from a distal end to a proximal end of the basket, the basket having an expanded state and a collapsed state;

spiraled wires that define a hollow channel extending from the proximal end of the basket to a proximal end of the spiraled wires;

a core wire with a proximal end and a distal end coupled to the distal end of the basket, the core wire extending

from the distal end of the basket through the hollow channel to the proximal end of the core wire, the proximal end of the core wire extending beyond the proximal end of the spiraled wires; and

a filter bag with a lip attached to the struts only at attachments located on the struts generally where the basket achieves its maximum diameter when the basket is in the expanded state for capturing emboli,

movement of the core wire in the proximal direction relative to the spiraled wires causing the basket, and hence the filter bag, to open to the expanded state, and movement of the core wire in the distal direction relative to the spiraled wires causing the basket, and hence to the filter bag, to close to the collapsed state.

11. The device of claim 10 wherein the number of struts is four.

12. The device of claim 10 wherein the opening of the filter bag faces toward the stenotic lesion.

13. The device of claim 10 wherein the filter bag is made of a mesh material.

14. The device of claim 10 wherein the filter bag is made of connective tissue including extracellular matrix.

15. The device of claim 14 wherein the extracellular matrix is made of small intestinal submucosa.

16. The device of claim 10 wherein the struts are made of shape memory material with a transition temperature.

17. The device of claim 10 wherein the struts are made of superelastic material.

18. The device of claim 17 wherein the superelastic material is Nitinol.

19. A method for embolic protection during treatment of a stenotic lesion in a body vessel, the method comprising:

disposing an embolic protection device in an undeployed state in the body vessel, the device comprising:

a basket with a set of struts extending from a distal end to a proximal end of the basket;

spiraled wires that define a hollow channel extending from the proximal end of the basket to a proximal end of the spiraled wires;

a core wire with a distal end coupled together with the distal end of the basket, the core wire extending from the distal end of the basket through the hollow channel to a proximal end of the core wire that extends beyond the proximal end of the spiraled wires; and

a filter bag with a lip attached to the struts only at attachments located on the struts approximately where the basket achieves its maximum diameter when the basket is in an expanded state for capturing emboli; and

moving the core wire relative to the spiraled wires to deploy the device in a deployed state downstream from the stenotic lesion to capture emboli during treatment of the stenotic lesion.

20. The method of claim 19 further comprising moving the core wire relative to the spiraled wires to close the basket to a collapsed state for retrieving the embolic protection device from the body vessel.